



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2021-D-0242, FDA-2021-D-0243, FDA-2021-D-0244, and FDA-2021-D-0245]

Compliance Policy Guide Sec. 555.400 Aflatoxins in Human Food; Compliance Policy Guide Sec. 570.200 Aflatoxins in Brazil Nuts; Compliance Policy Guide Sec. 570.375 Aflatoxins in Peanuts and Peanut Products; and Compliance Policy Guide Sec. 570.500 Aflatoxins in Pistachio Nuts; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of four final Compliance Policy Guides (CPG) entitled “Compliance Policy Guide Sec. 555.400 Aflatoxins in Human Food,” “Compliance Policy Guide Sec. 570.200 Aflatoxins in Brazil Nuts,” “Compliance Policy Guide Sec. 570.375 Aflatoxins in Peanuts and Peanut Products,” and “Compliance Policy Guide Sec. 570.500 Aflatoxins in Pistachio Nuts.” These CPGs revise the existing CPGs by updating the format and including references to other aflatoxins CPGs and a reference to the Memorandum of Understanding between the Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture (USDA) and FDA. The CPGs provide guidance for FDA staff on FDA’s current regulatory criteria for aflatoxins in human food, Brazil nuts, peanuts and peanut products, and pistachio nuts.

DATES: The announcement of the guidances is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include Docket No. FDA-2021-D-0242 for "Compliance Policy Guide Sec. 555.400 Aflatoxins in Human Food," Docket No. FDA-2021-D-0243 for "Compliance Policy Guide Sec. 570.200 Aflatoxins in Brazil Nuts," Docket No. FDA-2021-D-0244 for "Compliance Policy Guide Sec. 570.375 Aflatoxins in Peanuts and Peanut

Products,” and Docket No. FDA-2021-D-0245 for “Compliance Policy Guide Sec. 570.500 Aflatoxins in Pistachio Nuts.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidances to the Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4337, Silver Spring, MD 20993. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidances.

FOR FURTHER INFORMATION CONTACT: Mischelle Ledet, Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-701-5986.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of four CPGs for FDA staff entitled “Compliance Policy Guide Sec. 555.400 Aflatoxins in Human Food,” “Compliance Policy Guide Sec. 570.200 Aflatoxins in Brazil Nuts,” “Compliance Policy Guide Sec. 570.375 Aflatoxins in Peanuts and Peanut Products,” and “Compliance Policy Guide Sec. 570.500 Aflatoxins in Pistachio Nuts.” We are issuing these guidances consistent with our good guidance practices regulation (21 CFR 10.115). We are issuing these four CPGs as final and without first providing an opportunity to comment because the revisions are non-substantive; for example, we revised the CPGs’ formats to be consistent with other CPGs, included references to other aflatoxins CPGs, and included a reference to the Memorandum of Understanding between USDA/AMS and FDA. Given the minor nature of these revisions, an opportunity for public comment before we finalize the CPGs is unnecessary. However, as is the case for all guidance documents, the public may comment on any guidance document at any time (§10.115(g)(5)).

The guidances represent the current thinking of FDA on this topic. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

These four CPGs update the previously issued “CPG Sec. 555.400 Foods--Adulteration with Aflatoxin,” “CPG Sec. 570.200 Brazil Nuts--Adulteration with Aflatoxin,” “CPG Sec. 570.375 Aflatoxin in Peanuts and Peanut Products,” and “CPG Sec. 570.500 Pistachio Nuts--Aflatoxin Adulteration.” The CPGs are intended to provide guidance for FDA staff regarding adulteration in human food, Brazil nuts, peanuts and peanut products, and pistachio nuts due to the presence of aflatoxins and explain when we may consider such foods to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342).

II. Paperwork Reduction Act of 1995

These guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidances at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidances.

Dated: May 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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